CLAIMS

1. A process for the production of a vaccine composition of labile immunogens, wherein a fluid comprising one or more immunogens is sprayed into a reactor containing fluidised particles of a pharmaceutically acceptable water soluble material at a temperature of about 25°C to about 50°C, such that the immunogen coats and is dried onto the particles under the fluidising conditions, and thereafter collecting from said reactor dried immunogen containing particles having a moisture content between about 0.1% w/w to about 10% w/w so as to give a stabilised vaccine composition.

2. A process according to claim 1 wherein the immunogen comprises virus particles, bacterial cells or other microorganisms, or antigenic products thereof.

3. A process according to claim 2 wherein the immunogen comprises virus particles or bacterial cells.

4. A process according to claim 2 wherein the immunogen comprises a viral or bacterially derived immunogen selected from a protein, peptide, glycoprotein, or glycolipid, or polysaccharide, optionally associated with a carrier, which on immunisation of a subject provokes an immune response to the virus or bacteria from which the immunogen was derived.

5. A process according to claim 1 wherein the fluid comprising one or more immunogens is a viral vaccine or bacterial vaccine preparation mixed with a stabilising diluent to provide a fluid comprising viral particles or bacterial immunogens.

6. A process according to claim 1 wherein the temperature is from about 30°C to about 46 °C.

7. A process according to claim 1 wherein the moisture content is from 0.1% w/w to 2.6% w/w.

8. A process according to claim 7 wherein the moisture content is from 0.2% w/w to 1.5% w/w.

9. A process according to any one of claims 1 to 8 wherein said fluid comprising one or more immunogens is a suspension or dispersion of immunogens selected from viral particles, bacterial cells or other microorganisms, eukaryotic cells, or anitgenic products of said immunogens.

10. A process according to any one of claims 1 to 9 wherein said fluid containing one or more immunogens includes one or more amino acids, proteins, chelating agents, buffers, preservatives, stabilisers, mineral salts, metal antioxidants, lubricants and adjuvants.

11. A process according to claim 9 wherein viral particles or bacterial cells in a culture medium, vaccine composition or other fluid are diluted with a diluent.

12. A process according to claim 1 wherein said particles of a pharmaceutically acceptable water soluble material comprise one or more monosaccharide, disaccharide, polysaccharide, carbohydrate, water soluble peptide, mineral salt, water soluble polymer, or water soluble pharmaceutically acceptable excipient.

13. A process according to any of claims 1 to 12 wherein said pharmaceutically acceptable water soluble material comprises one or more sugars.

14. A process according to any of claims 1 to 13 wherein the pharmaceutically acceptable water soluble material comprises a particle size from 20 microns to 1 mm.

15. A process according to claim 14 wherein said particle size is from 50 microns to 200 microns.

16. A process according to any of claims 1 to 15 wherein said reactor is a spray drying reactor or fluidized bed into which immunogen containing fluid is sprayed onto fluidized particles and dried thereon.

17. A process according to claim 16 wherein fluid comprising one or more immunogens is sprayed through a nozzle or spray head which delivers the sprayed fluid into the reactor.

18. A process according to claim 16 wherein said particles are fluidized in a reactor containing a fluidized bed at a rate between 200 to 500 m^2/h.

19. A process according to claim 1 wherein said stabilised vaccine composition is stable and efficacious on storage at 25°C for 30 days.

20. A process according to claim 1 wherein the vaccine composition is a free flowing particulate material.

21. A process according to any of claims 1 to 20 which further comprises mixing together two or more free flowing stabilised vaccine compositions containing different immunogens to give a multivalent vaccine composition.

22. A process according to claim 3 wherein said virus particles or bacteria is a carrier for the delivery of DNA sequences, RNA sequences or vaccine antigens.

23. A process according to claim 3 wherein said virus particles or bacteria are genetically modified.

24. A stabilised vaccine composition comprising immunogen coated particles of a pharmaceutically acceptable water soluble material, the composition having a moisture content between about 0.1% w/w to about 10% w/w.

25. A vaccine composition according to claim 24 wherein the immunogen comprises virus particles, bacterial cells or other microorganisms or antigenic products thereof.

26. A vaccine composition according to claim 24 wherein the immunogen comprises virus particles or bacterial cells.

27. A vaccine composition according to claim 26 which contains live virus particles capable of reproduction in an immunised host.

28. A vaccine composition according to claim 24 wherein the immunogen comprises a viral or bacterially derived immunogen selected from a protein, peptide, glycoprotein, or glycolipid, or polysaccharide, optionally associated with a carrier, which on immunisation of a subject provokes an immune response to the virus or bacteria from which the immunogen was derived.

29. A vaccine composition according to claims 24 to 28 which is stable and efficacious on storage at 25°C for 30 days.

30. A vaccine composition according to claims 24 to 29 wherein the pharmaceutically acceptable water soluble material comprises one or more of a monosaccharide, disaccharide, polysaccharide or carbohydrate, water soluble peptide or peptides, gelatine, mineral salt or water soluble polymer, or water soluble pharmaceutically acceptable excipient.

31. A vaccine composition according to claim 30 wherein said water soluble material comprises one or more sugars.

32. A vaccine composition according to claim 24 comprising two or more different immunogen coated particles, so as to give a multivalent vaccine.

33. A vaccine composition according to any of claims 24 to 32 wherein the immunogen is a carrier of a nucleic acid sequence or a peptide or polypeptide.

34. A vaccine composition according to any of claims 24 to 33 which comprises a particle size from 50 microns to 400 microns.

35. A process according to claim 34 wherein said particle size is from 50 microns to 200 microns.

36. A composition according to any of claims 24 to 35 wherein said immunogen coated particles include one or more amino acids, proteins, chelating agents, buffers, preservatives, stabilisers, mineral salts, antioxidants, lubricants and adjuvants.

37. A vaccine composition according to claim 24 which is a free flowing particulate composition.

38. A vaccine composition according to claims 24 to 37 which is immunogenic on administration to an animal or human.

39. A vaccine composition according to claims 24 to 37 which is a human or animal vaccine.

40. A vaccine according to claim 39 which is a poultry vaccine for the prevention of Newcastle Disease, infectious bronchitis, coccidiosis, fowl pox, fowl cholera, reovirus induced tenosynovitis (viral arthritis), fowl laryngotracheitis, avian encephalomyelitis, infectious bursal disease (IBD), Marek's Disease, salmonella infection, mycoplasma gallisepticum infection, avian rhinotracheitis, avian herpes and Mycoplasma hyponeumoniae, Egg Drop Syndrome, Infectious Coryza (Haemophilis pasagallinarum), mycoplasma synoviae or avian reovirus.

41. A vaccine composition according to claim 39 which is a porcine vaccine, for the prevention or treatment of Actinobacillus pleuropneumoniae, atrophic rhinitis, pseudorabies, swine erysipelas, porcine parvovirus, E-coli enterotoxicosis, myoplasma hyopneumoniae, influenza, leptospira, E.-coli infection, Porcine Reproductive and Respiratory Syndrome (PRRS), Bordetella and multocida types A and D infections, haemophilus parasuis infection, clostridium perfringens infection, rotavirus infection, Streptococcus suis infection, Glasser's Disease, pneumonia, bordetella bronchiseptica infection..

42. A vaccine according to claim 39 which is a human vaccine for the prevention of influenza, hepatitis A, hepatitis B, hepatitis C, herpes simplex virus (type 2), polio, diphtheria, pertussis, haemophilus influenza type B (Hib), measles, mumps, rubella, typhoid fever, varicella (chicken pox), Dengue fever, Epstein-Barr virus infection, human papillomavirus infection, Streptococcus pneumoniae infection, Neisseria meningitidis infection, Pneumococcal infection, viral meningitis, rotavirus infection, tick-borne encephalitis, travel diarrhea, cholera, yellow fever or tuberculosis.